UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

EUGENE DIVISION

JOAN LAFFERTY,

Plaintiff,

v.

PROVIDENCE HEALTH PLANS AND EUGENE FREEZING AND STORAGE GROUP HEALTH PLAN,

Defendant.

08-CV-6318-TC

OPINION AND ORDER

COFFIN, Magistrate Judge:

This is a case about insurance coverage for treatment of a malignant brain tumor. At all relevant times, plaintiff Joan Lafferty (Lafferty) was a participant in the Eugene Freezing and Storage Group Health Plan (Plan), which is insured by Providence Health Plans (Providence). She brings this action under the Employee Retirement Income Security Act of 1974 (ERISA), 29 USC §§ 1001-1461, to obtain coverage for high dose chemotherapy enhanced by Blood Brain Barrier disruption

(BBBD) treatment to treat her primary central nervous system lymphoma (PCNSL)[1], a rare malignant brain cancer. The BBBD treatment utilizes a relatively inexpensive drug, Mannitol, to disrupt the blood brain barrier, thus allowing chemotherapy drugs to cross the barrier. The BBBD treatment has been effective in treating Lafferty's cancer. Providence has denied coverage of Lafferty's claims directly associated with her BBBD treatment.

The parties have filed cross motions for judgment pursuant to FRCP 52. The parties have consented to allow a Magistrate Judge to decide this case in accordance with FRCP 73 and 28 USC § 636(c). For the reasons set forth below, I grant Lafferty's motion and deny defendants' motion.

Undisputed Facts

At all relevant times, Lafferty was a participant as defined in the Plan. (Doc. 44; SR[2] 619). The Plan is an employee benefits plan covered under ERISA, 29 USC §§ 1002(1) and 1003(a). Providence is the sponsor of the Plan within the meaning of ERISA, 29 USC § 1002(16)(B), and also is the administrator of the Plan under 29 USC §§ 1002(16)(A). The Plan documents include the Group Contract, which is also referred to as the Providence Policy (Policy) and the Oregon Open Option Member Handbook, also referred to as the Summary Plan Description (SPD).

The Policy expressly provides that Providence has "the discretionary authority to interpret the terms of the related ERISA plan, to make factual determinations relevant to benefit determinations and to otherwise decide all questions regarding eligibility for benefits under the plan..." and that Providence's determinations regarding the Plan's provisions "shall not be subject to

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[1]PCNSL is also referred to as primary CNS lymphoma in the record.

[2]"SR" refers to the stipulated record filed by the parties on June 24, 2009, which is docket # 30.

challenge absent a finding that such determination...is arbitrary and capricious." (SR 601). The SPD does not contain this language. (SR 636-715). The SPD does, however, state that the SPD "is not complete without your: Summary of Benefits and any other supplemental summary documents." (SR 642). The SPD also states that a participant may sometimes need "more detailed information" and in this event, the participant should request a copy of the "Employer Group Contract–a legal document which explains your benefits, rights and obligations in more detail." (SR 642).

At all relevant times, Providence had a policy declaring blood-brain-barrier disruption treatment not a covered benefit because it was not demonstrated to be "safe and efficacious." (Decl. of James H. MacKay, MD, Ex. 2 (dkt. #36-2)). Providence required prior authorization for BBBD treatment. (Id.) Providence's Policy defined experimental treatment as follows:

> *Experimental/Investigational* means those services that are determined by *Us* not to be *Medically Necessary* or accepted medical practice in the *Service Area*, including *Services* performed for research purposes. In determining whether *Services* are *Experimental/Investigational*, *We* will consider whether the *Services* are in general use in the medical community in the U.S.; whether the *Services* are under continued scientific testing and research; whether the *Services* show a demonstrable benefit for a particular illness or disease; whether they are proven to be safe and efficacious; and whether they are approved for use by appropriate governmental agencies. We determine on a case-by-case basis whether the requested *Services* will result in greater benefits than other generally available *Services*, and will not approve such a request if the *Service* poses a significant risk to the health and safety of the *Member*. We will retain documentation of the criteria used to define a *Service* deemed to be *Experimental/Investigational* and will make this available for review upon request.

(SR 550)(italic in original). The parties agree that BBBD treatment is accepted medical practice in the service area, which is Oregon. (SR 525). The parties also agree that BBBD treatment is under continued scientific testing and research in that such treatment has not undergone Phase III trials. (SR 84, 525).

Lafferty was diagnosed with PCNSL in July 2007 when she was 61 years old. (SR 20).

Lafferty submitted a request to Providence for coverage of BBBD therapy at Oregon Health and Sciences University (OHSU) on July 27, 2007. (SR 14). On August 1, 2007, Lafferty began BBBD treatment, and, on the same day, Providence notified her that BBBD treatment was not covered under her health plan because it was determined to be "investigational/experimental." (SR 74, 68).

On August 3, 2007, Dr. Edward Neuwelt, Lafferty's treating physician at OHSU, faxed Providence a request for reconsideration of the coverage denial. (SR 84-153). Dr. Neuwelt's request for reconsideration noted that there was no "universally accepted gold standard" of care for PCNSL because, due to the rarity of this type of cancer, there had been no Phase III randomized trials for treatment. (SR 84). About 12 days later, on August 15, 2007, Providence notified Dr. Neuwelt by letter that it had considered his request for reconsideration but was upholding the denial because BBBD treatment is considered investigational "as long term studies have not been completed; therefore [the BBBD] would not be a covered benefit." (SR 164).

Erik Finrow, Eugene Freezing and Storage's insurance agent, contacted Providence to inquire about coverage for Lafferty's BBBD treatment. (SR 201-203). On August 30, 2007, Providence Review Manager Cynthia Smith sent an email related to Finrow's inquiry to Providence Account Manager Rachelle Nerseth stating that Providence's Medical Director had recommended an external review of the BBBD protocol by Stacey Lewis and that in the past 3 years, out of 145 requests for BBBD treatment coverage, Providence had approved and paid 24. (SR 201-202). Finrow sent Nerseth an email on September 5, 2007 indicating that Eugene Freezing and Storage was not going to renew if Providence continued to decline Lafferty's BBBD coverage. Finrow stated "I understand their frustration, mainly because Providence had paid this in the past....It seems to me the departure of one of OHSU's main Oncologists, who went to Providence has something to do with the change

in oppnion [sic]. ...this claim denial seems fishy." (SR 201). A September 6, 2007 email from Nerseth stated that Finrow's research which indicated that Providence was not the only carrier that considered BBBD experimental and denied coverage "help[ed] to support [Providence's] position in regards to this treatment." (SR 203).

On September 7, 2007, Providence requested that Stacy Lewis, MD review its denial of Lafferty's request for BBBD treatment. Dr. Lewis is the Medical Director of Providence's Cancer Center; however, she is not a Providence Health Plan representative for purposes of Providence's grievance and appeal process. (Decl. of Gerald Corn, MD ¶ 5 (dkt.#35)). In response to the three specific questions Providence posed, Dr. Lewis responded that: (1) BBBD treatment was investigational; (2) other treatment options were systemic chemotherapy with or without brain radiation; and (3) systemic chemotherapy with or without brain radiation was the standard care of treatment for PCNSL (SR 206).

Lafferty's husband submitted a written initial grievance of Providence's denial of coverage on September 17, 2007. (SR 208). On September 19, 2007, Providence's Medical Director, Gerald Corn, MD, was asked to advise whether the denial of coverage should be upheld, and Tammy Buell, RN gathered the documents for Dr. Corn to review. (SR 215; decl. of Gerald Corn, MD ¶¶ 6-7 (dkt.#35)). By letter dated September 26, 2007, Providence's Quality Medical Management Committee denied Lafferty's initial grievance on the grounds that BBBD was investigational and therefore not covered. (SR 221).

By letters dated November 19 and November 20, 2007, Lafferty requested her first level appeal of the initial grievance denial. (SR 234-239). Lafferty's letter described how much her condition had improved after receiving BBBD treatment–she was again able to walk unassisted and

her tumor had shrunk to "just a spot." (SR 235-239). Nurse Buell again gathered documents for review of Lafferty's first level appeal. (SR 242). Kevin Keck, MD, reviewed Lafferty's First Level Appeal, and on November 27, 2007, advised that the BBBD treatment was experimental. (SR 242; decl. Kevin Keck, MD, ¶ 6 (dkt.#34)). By letter dated November 28, 2007, the QMM committee upheld the previous denial of coverage. (SR 244).

On December 11, 2007, plaintiff requested a second level appeal before the Providence Grievance Committee. (SR 247). On December 28, 2007, Lafferty, Dr. Neuwelt, her then-counsel, and her husband appeared before the Grievance Committee, which included Dr. Corn and Nurse Buell, RN. (SR 396). In a December 31, 2007 email, Dr. Corn asked Walter Urba, MD to review Lafferty's BBBD coverage claim. (SR 468). Dr. Urba, who is an oncologist, is the Director of Providence's Robert W. Franz Cancer Research Center and the physician Director of Research for Providence Health & Services in Oregon. (SR 468). Providence sent a follow-up letter to Dr. Urba on January 7, 2008, noting that the rationale for Providence's denials was that BBBD treatment was "investigational in nature." (SR 419). Three days later, on January 10, 2008, Lafferty's counsel sent Providence a letter expressing puzzlement at the Grievance Committee's "efforts to get 'further medical review.'" (SR 421). Lafferty's counsel requested the opportunity to participate in selecting an outside reviewer and to respond to any adverse opinion. (SR 421). In a January 18, 2008 email to Dr. Corn, Dr. Urba opined that BBBD treatment was experimental and the standard treatment would be chemotherapy with or without radiation. (SR 424; 467).

Providence also asked William Flood, MD, an oncologist with International Treatment Partners (ITA) to review Lafferty's treatment plan. (SR 425). In a report dated February 15, 2008, Dr. Flood opined that BBBD treatment is not the standard of care for PCNSL and that such treatment

was investigational/experimental under Lafferty's Plan. (SR 425).

At Providence's invitation, Lafferty also submitted additional information for the Grievance Committee to review. (SR 465, 513-21). Included in her supplemental submissions was Lafferty's contention that the Grievance Committee must consider 9 questions suggested by the Plan language before determining whether BBBD treatment was experimental/investigational. (SR 477-80).

Providence sent Lafferty a letter dated April 16, 2008, notifying her that the Grievance Committee had denied her appeal. (SR 523-29). Having exhausted her remedies with Providence, Lafferty filed this lawsuit on October 14, 2008.

Standard of Review

Each of the parties moves for judgment in its favor on Lafferty's ERISA claims under FRCP 52. Under Rule 52, the court conducts what is essentially a bench trial on the record, evaluating the persuasiveness of conflicting testimony and deciding which is more likely true. Kearney v. Standard Ins. Co., 175 F3d 1084, 1094-95 (9th Cir 1999). ERISA provides Lafferty with a federal cause of action to recover benefits she claims are due under the Plan. 29 USC § 1132(a)(1)(B). ERISA does not specify a standard of review. Courts apply a de novo standard unless the benefit plan gives the administrator discretion to determine eligibility for benefits; if the plan does grant such discretionary authority the decision is reviewed for abuse of discretion. Firestone Tire & Rubber Co. v. Brunch, 489 U.S. 101, 115 (1989); Saffron v. Wells Fargo & Co. Long Term Disability Plan, 552 F3d 863, 866 (9th Cir 2008). However, if the plan administrator engages in "flagrant violations of the procedural requirements of ERISA," a court applies a de novo standard of review, even if the Plan contains a grant of discretionary authority. Abatie v. Alta Health and Life Ins. Co., 458 F3d 955, 971 (9th Cir 2006).

No deference to the plan administrator is given under de novo review. In contrast, under the arbitrary and capricious standard of review, an administrator's decision "is not arbitrary unless it is 'not grounded on any reasonable basis.'" Horan v. Kaiser Steel Ret. Plan, 947 F2d 1412, 1417 (9th Cir 1991), quoting Oster v. Barco of Cal. Employees' Ret. Plan, 869 F2d 1215, 1219 (9th Cir 1988). Also, an arbitrary and capricious standard of review limits the court's consideration to evidence reviewed by the plan administrator at the time the eligibility decision was made. McKenzie v. Gen. Tel. Co. of Cal., 41 F3d 1310, 1316 (9th Cir 1994).

Which standard of review applies depends primarily on the plan's terms. A plan confers discretion when it "includes even one important discretionary element, and the power to apply that element is unambiguously retained by its administrator." Bogue v. Ampex Corp., 976 F2d 1319, 1325 (9th Cir 1992).

Lafferty contends the standard of review should be de novo because: (1) Providence failed to include a discretionary grant in its Summary Plan Description (SPD), creating a conflict between the SPD and the Policy, which includes a discretionary grant; and (2) even if there is no conflict between the Plan documents, Providence committed flagrant violations of ERISA's mandatory regulations. Providence contends that the Policy controls over a silent SPD, and, in any event, no conflict exists between the Policy and the SPD. Providence also denies flagrant ERISA procedural violations. Accordingly, Providence urges the court to apply the arbitrary and capricious standard of review.

A. Conflict Between the Policy and SPD

The parties agree that the Policy contains language granting Providence discretionary authority and that the SPD is silent on this issue; however, they dispute the implications of the SPD's

silence. (Plf.'s Opening Memorandum, p. 9 n. 7,(dkt.#27)). Lafferty argues the silence creates a material conflict between plan documents and urges this court to consider only the SPD, which is more favorable to her, when determining the proper standard of review. Providence maintains that the SPD's silence does not conflict with the language granting discretionary authority in the Policy; thus the Policy language controls the review standard. I find that the plan documents do not conflict.

When interpreting an ERISA plan, a court must construe the plan documents as a whole. Bergt v. Ret. Plan for Pilots Employed by MarkAir, Inc., 293 F3d 1139, 1143 (9th Cir 2002). The SPD is part of the plan documents. Id. Because a court must consider the Policy's and the SPD's language, an issue arises when the two documents contain conflicting provisions. Id. If there is a "material conflict" between the plan documents, a court may focus on one plan document instead of construing the documents as a whole. Id. In that instance, the document more favorable to the participant controls. Id.

The instant case is distinguishable from cases which have found material conflicts between the SPD and the Policy. In those cases, the SPD and the Policy contained inconsistent language. See e.g., Wiley v. Cendant Corp. Short Term Disability Plan, 631 FSupp2d 1221, 1224-26 (ND Cal 2009)(finding a conflict where the SPD granted broad discretion to an employee benefits committee and limited discretion to the plan administrator while the plan contract granted broad discretion to the plan administrator). Here, the Policy language grants Providence discretionary authority while the SPD is silent. The Ninth Circuit, and the majority of other jurisdictions which have considered this issue, have concluded that silence in the SPD regarding language contained within the plan is not necessarily a conflict. Atwood v. Newmont Gold Co. Inc., 45 F3d 1317, 1321 (9th Cir 1995)(overruled on other grounds by Abatie v. Alta Health and Life Ins. Co., 458 F3d 955, 966 (9th

Cir 2006); Tocker v. Phillip Morris Companies, 470 F3d 481, 489 (2d Cir 2006); Charter Canyon Treatment Ctr. v. Pool Co., 153 F3d 1132, 1136 (10th Cir 1998); Mers v. Marriott Int'l Group Accidental Death and Dismemberment Plan, 144 F3d 1014, 1023 (7th Cir 1998); see also, Burnstein v. Ret. Account Plan for Employees of Allegheny Health Educ. & Research Found., 334 F3d 365, 379 (3d Cir 2003)("it would defeat the purpose of having a summary of a full plan document if the SPD were to parrot all the terms of the plan document"). As another court observed: "to equate silence with conflict would necessarily reduce any pension plan description to an absurd result since by its own definition the summary plan is meant to summarize, not recite, the detailed pension plan." Nash v. Mercedes Benz USA, et. al., 489 FSupp 2d 411, 416 (D NJ 2007) (emphasis in original).

This case does not present a situation where the SPD fails to accurately describe circumstances which might affect a participant's eligibility for benefits. The SPD is specific enough to "enable the ordinary employee to sense when there is a danger that benefits could be lost or diminished." Atwood, 45 F3d at 1321. The SPD states that "Providence has the legal right to determine which medical conditions are covered by our plan" and "reserves the right to deny payment for services that are judged not to meet the criteria maintained by us to determine medical necessity." (SR 653). The disclaimer contained in the SPD that it is not complete without the Policy further supports the conclusion that the SPD was specific enough to warn Plan participants that Providence retained the discretion to interpret the terms of the Plan. Atwood, 45 F3d at 1321. In keeping with the majority of the courts that have considered this issue, I find that the SPD's silence does not create a material conflict and the Policy language controls. However, my inquiry into what review standard applies does not end here.

B. Flagrant Violations

Lafferty contends that despite the Policy language, the correct standard of review is de novo because Providence flagrantly violated ERISA's procedural requirements. Providence argues that there were no flagrant violations of ERISA's procedures during the review process. I find that Providence failed to follow the applicable procedures and that such failures were wholesale and flagrant violations of ERISA, subjecting Providence's decision to de novo review.

In Abatie, the Ninth Circuit clarified the standard of review that district courts should apply when administrators fail to follow ERISA's procedural requirements. Abatie, 458 F3d at 971. "Procedural violations of ERISA do not alter the standard of review unless those violations were so flagrant as to alter the substantive relationship between the employer and employee, thereby causing the beneficiary substantive harm." Gatti v. Reliance Standard Life Ins. Co., 415 F3d 978, 985 (9th Cir. 2005). ERISA seeks to promote a good faith bilateral exchange of information on the merits of the claims between the administrator and the claimant. Jebian v. Hewlett-Packard Co. Employee Benefits Org. Income Prot. Plan, 349 F3d 1098, 1107 (9th Cir. 2003). Thus, in the context of an ongoing, good faith information exchange, "inconsequential violations of the deadlines or other procedural irregularities would not entitle the claimant to de novo review. Gilbertson v. Allied Signal, Inc., 328 F3d 625, 635 (10th Cir. 2003)(emphasis added).

ERISA provides that "every employee benefit plan shall afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the plan." 29 CFR § 1133(2); 29 CFR § 2560.503-1(h)(1). To afford a full and fair review, a plan must provide for "a review that does not afford deference to the initial adverse benefit determination and that is conducted by an appropriate named fiduciary of the plan who is neither the individual who made the adverse determination that is the subject of

appeal, nor the subordinate of such individual." 29 CFR 2560.503-1(h)(2),(3)(ii),(4). The plan must "[p]rovide that, in deciding an appeal of any adverse benefit determination that is based in whole or in part on a medical judgment, the appropriate named fiduciary shall consult with [an appropriate] health care professional who was [not] consulted in connection with the adverse benefit determination that is the subject of the appeal[.]" 29 CFR § 2560.503-1(h)(3)(iii)-(v), 4.

The record reveals that Dr. Corn signed the physician reviewer's denial of Lafferty's initial grievance and also was a member of the Grievance Committee that denied Lafferty's second level appeal. (SR 215, 396; Tr. 33:20-25, 34:1-16 (dkt.#57)). Providence attempts to characterize Dr. Corn's involvement on two levels as inconsequential for two reasons: first, because the Grievance Committee is a separate entity made up of several people–not just Dr. Corn; and next, because Dr. Corn was a non-voting member of the Grievance Committee who "advise[d] lay people on the committee as to what they should do." (Tr. 34:13-15(dkt. #57)). Under ERISA's "full and fair" review requirement, once Dr. Corn signed the physician reviewer's denial of Lafferty's initial grievance, he should have been removed from the review process. Instead, Dr. Corn appeared on the Committee reviewing Lafferty's final appeal to "advise lay people [on the Grievance Committee] as to what they should do." This is almost more egregious than Dr. Corn having only one vote on the Grievance Committee; while he may have had no votes, he was in a position to potentially influence the votes of every other person on the Grievance Committee. Providence characterizes Lafferty's argument as being that Providence violates the "'fresh eyes' requirement whenever Providence personnel who are knowledgeable about a grievance even speak with those involved in appeals as the grievance process wends its way up the appeal chain." (Dkt. #100, p. 4, n. 1). However, the record here shows that Dr. Corn did more than speak to those involved in subsequent appeals; he advised

them on what they should do. (Tr. 34:13-15(dkt. #57)). Undoubtedly, having the individual who made the adverse decision which is being appealed serve on and advise the voting members violates ERISA's procedural requirements.

As well as participating in two levels of Lafferty's appeal process, the record shows that Dr. Corn sought further medical review of Lafferty's claim after the hearing before the Grievance Committee. (SR 468). In an email dated December 31, 2007, Dr. Corn requests that Walter Urba, MD review Lafferty's case and give Providence a second opinion. (SR 468). In his request for a second opinion, Dr. Corn stated: "the CMS website and every health plan website we've reviewed has stated that BBBD treatment is 'experimental/investigational.' Ed [Neuwelt], of course, rejects this designation." (SR 468). After Dr. Urba agreed to review Lafferty's case, Dr. Corn sent an email thanking him and stating that he would "limit the material we send you for review, and really, the only question is is [sic] Blood-brain Barrier Disruption Chemotherapy for Primary CNS Lymphoma investigational/experimental or not?" (SR 467). The record shows that Dr. Corn was involved in two levels of review, as well as in gathering information for further medical review–materials which, by his own admission, he limited. I do not find Providence's assertion that this does not violate ERISA because there is no requirement that the participants at each level of appeal to be different persuasive. Dr. Corn was undeniably involved in multiple levels of review: he denied Lafferty's initial grievance; he advised lay people on the Grievance Committee, and he gathered information for further medical review after the December Grievance Committee Hearing. I find that this contravenes ERISA's goal to to promote a good faith bilateral exchange of information on the merits of the claims between the administrator and the claimant. Jebian, 349 F3d at 1107 (9th Cir. 2003).

Tammy Buell, RN, a Providence nurse, gathered information for Lafferty's initial grievance

and first level review, was a member of the Quality Medical Management (QMM) group, which made decisions on Lafferty's initial grievance and first level appeal, and served, as an non-voting advisory member, on the Grievance Committee. (SR 215, 221, 242, 244, 396; decl. Mark Jensen ¶ 4 (dkt. #102)). The Policy requires that the first level appeal/second level appeal be reviewed by employees who were not involved in reviewing the initial grievance. (SR 590). While Nurse Buell's role as a gatherer of information is not troubling, her participation in both the QMM group and the Grievance Committee is cause for concern. Providence contends that ERISA does not require that every tangential participant at each level of review be different, and, moreover, the Dr. Corn, not the QMM committee, actually decided Lafferty's initial grievance despite the fact that QMM sent the denial letter. The record, however, shows that Nurse Buell was involved with Lafferty's grievance of her benefit denial from the beginning to the end when she advised members of the Grievance Committee. (SR 215; decl. Mark Jensen, ¶4 (dkt. #102)). According to the record, the "QMM completed a detailed evaluation of [Lafferty's] case...[and] decided to uphold the previous denial based on the analysis and terms outlined below." (SR 221). Despite Providence's assertions that only Dr. Corn made the initial grievance denial decision[3], I cannot ignore the language of Providence's own letter, which clearly states that the QMM decided to uphold the denial. (SR 221). Indeed, it appears from the body of the letter that the Medical Director's (Dr. Corn's) determination that BBBD treatment was experimental formed part of the basis for the QMM's decision. (SR 221). I find that Nurse Buell's participation in on both the QMM committee and the Grievance Committee as an advisory member violates ERISA's procedural guidelines.

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[3]As previously noted, Dr. Corn signed a physician reviewer's form denying Lafferty's appeal (SR 215), but I find that this does not show that only Dr. Corn participated in the denial decision, especially when the letter's language clearly indicates otherwise.

Lafferty alleges, based on Providence's internal notations, that Providence violated ERISA's procedures by improperly consulting Stacy Lewis MD in the pre-authorization denial and the initial grievance denial. I find that Providence improperly relied on Dr. Lewis's opinion on two review levels because Providence states in its Memorandum in Support of Cross Motion for Judgment that Dr. Corn, a general practitioner, and Dr. Keck, an internist, both relied on Dr. Lewis's opinion in making decisions on different appeal levels; Dr. Corn in the physician's review of Lafferty's initial grievance, and Dr. Keck in the first level appeal. (Dkt. #33, p. 21). To rely on Dr. Lewis's opinion for these two levels of review violates ERISA regulation 29 CFR 2560.503-1(h)(3)(v).

Lafferty alleges two other violations of ERISA's procedural requirements: (1) failure to engage qualified experts at two levels; and (2) failure to advise Lafferty what was needed to perfect her claim. I cannot find that these alleged actions resulted in ERISA violations. First, as noted above, Providence consulted Stacy Lewis, a board certified oncologist and Medical Director of Providence's Hospital's Cancer Center. (Def.'s Mem., p. 21(dkt. #33)). Even though Dr. Lewis was improperly consulted at two appeal levels, it is clear that Dr. Lewis is a "health care professional who has appropriate training and experience" in the field of oncology. 29 CFR 2560.503-1(h)(3)(iii). Next, Lafferty's claim was denied for being investigative or experimental. There is no evidence in the record indicating a deficiency in the materials Lafferty submitted in support of her appeals. Instead, the evidence shows that Lafferty submitted numerous materials for Providence's review.

I find that the significant procedural irregularities in the review process altered the substantive relationship between Providence and Lafferty, thereby depriving Lafferty of the right to appeal and causing substantive harm. Such significant procedural irregularities amount to acts which disregard the underlying purposes of ERISA. Accordingly, the applicable standard of review in this case is de

novo.

Discussion

I. Background

A. Primary Central Nervous System Lymphoma

PCNSL is an aggressive, highly malignant brain tumor that has the potential for dramatic response to chemotherapy. (SR 84, 124). However, because PCNSL is so aggressive, to sustain a durable response, it is necessary to treat the patient "with as much chemotherapy drug as possible in a concentrated time period." (Aff. Edward A. Neuwelt MD, ¶ 19, (dkt #46)). Because it is so rare, there have been no phase III randomized trials for PCNSL treatment; in other words, "the optimal treatment for PCNSL has yet to be defined." (SR 85, 298). One of the problems with treating PCNSL is that the tumor is inside the blood brain barrier, endothelial cells which line the brain capillaries, forming tight junctions with one another, and limiting the passage of most drugs from the blood stream to the other side of the blood brain barrier. (SR 146; Aff. Edward A. Neuwelt, MD, ¶¶ 4-5, dkt. #46)). The blood brain barrier limits chemotherapeutic drugs from reaching the tumor site. (Id.) "The standard treatment often involves high-dose methotrexate-based chemotherapy and whole brain radiation." (SR 124). This treatment prolongs survival, but, especially for patients over sixty, results in a substantial risk of damage to the patients central nervous system, causing loss of cognitive function. (SR 124, 85). Given this risk, most patients 60 years of age or older are treated with high-dose methotrexate-based chemotherapy alone. (SR 124).

B. Blood Brain Barrier Disruption Treatment

BBBD treatment is achieved by infusing Mannitol through an intra-cranial artery via the femoral artery. (Aff. Edward A. Neuwelt, MD, ¶ 7, dkt. #46)). Mannitol is a diuretic which

withdraws intracellular water from the endothelial cells which form the blood brain barrier, thereby causing the endothelial cells to shrink. (Id.) As the endothelial cells shrink, the tight junctions between them loosen, causing gaps between adjacent cells. (Id.) This gap allows the chemotherapeutic drugs, which are also delivered intra-arterially, to pass through the blood brain barrier and reach the tumor. (Id.) The blood brain barrier remains open for about an hour after it is disrupted. (Id.) BBBD treatment is a method of enhancing chemotherapy by increasing the dose intensity of chemotherapeutic drugs which reach the tumor. (SR 120).

C. Lafferty's Blood Brain Barrier Disruption Treatment

Laffery began receiving high dose chemotherapy enhanced with BBBD treatment in August 2007. (SR 171). Her treating physician was Dr. Neuwelt. (SR 170; aff. Edward A. Neuwelt, MD, ¶ 23, (dkt. # 46)). Dr. Neuwelt is a board certified neurosurgeon and a fully fellowship trained neuro-oncologist. (Aff. Edward A. Neuwelt, MD, ¶ 1, (dkt. # 46)). He is an internationally known expert in neuro-oncology and has been treating PCNSL at OHSU for over 25 years. (Id.) His OHSU group has treated one of the largest series of PCNSL patients in the United States. (SR 84).

The high dose chemotherapy enhanced with BBBD treatment involves a three day hospital stay. On the first day, the patient is admitted to the hospital and sent for a chest X-ray and a MRI scan of the brain to assess tumor response. After completing these tests, the patient moves to a bed on the oncology ward and IV hydration, which continues for the duration of the hospital stay, is started. The patient receives intravenous Rituxamab in the evening. (SR 84).

Over the next two days, the patient undergoes general anesthesia and then intra-arterial cauterization to access an intra-cranial vessel. This is followed by an intra-arterial infusion of 25% Mannitol to temporarily osmotically alter the blood-brain barrier. The patient next receives intra-

arterial Methotrexate and Carboplation. The total chemotherapy doses are Methotrexate 5000mg and Carboplatin 400mg/m2. The patient is admitted monthly for this procedure for a total of 12 courses, which equal 24 treatments, as there are 2 treatments during each course. (SR 85).

The challenge in treating PCNSL is that the blood-brain barrier limits chemotherapeutic drugs from reaching the tumor. Specifically, the blood-brain barrier is more permeable in the center of a malignant tumor because the tumor disrupts the cells which form the blood-brain barrier. (Aff. Edward A. Neuwelt, MD, ¶¶ 5-6, (dkt. # 46)). The blood-brain barrier at the outer ring of the tumor is less affected by the tumor, and thus, less permeable. (Id.) When a patient is treated without using a blood-brain barrier disruption drug such as Mannitol, this lower permeability at the outside ring of the tumor results in reduced concentrations of chemotherapeutic agents in-filtering at the tumor's periphery where there is active tumor growth. (Id.) OHSU's PCNSL treatment survival rates match or exceed the results from any other institution in the world and are achieved without cognitive loss. (Id. at ¶ 9.) All of OHSU's BBBD treatment protocols are approved by the Oregon Cancer Center, OHSU's institutional review board, and the Portland Veteran's Medical Center. All of the chemotherapeutic agents are standard chemotherapy drugs and are approved by the FDA. (SR 85).

When Lafferty began treatment at OHSU in August 2007, she was extremely ill and she was rapidly deteriorating– within a period of 10 days, she had deteriorated from being unsteady on her feet to having a complete paralysis of her right arm and leg. (SR 236; aff. Edward A. Neuwelt, MD, ¶¶ 24-25, (dkt. # 46)). Lafferty's health dramatically improved following her first treatment. (SR 236). She completed her treatment in July 2008 and has had a complete response to her high dose chemotherapy enhanced with BBBD. (Aff. Edward A. Neuwelt, MD, ¶¶ 26, (dkt. # 46)). Her July 2009 MRI was negative for disease reoccurrence and she has full cognitive function. (Aff. Edward

A. Neuwelt, MD, ¶¶ 26, (dkt. # 46); SR 237).

D. Coverage for BBBD Treatment Under the Policy

At the time Lafferty sought coverage for high dose chemotherapy enhanced with BBBD treatment, Providence's Policy specifically stated that the BBBD service was not covered and required prior authorization for this service. (Decl. James MacKay, MD, Ex. A, (dkt. 36-2)). The Policy stated that BBBD "services have not been demonstrated through prevailing peer-reviewed medical literature, or long-term outcome studies to be safe and efficacious." The Policy states that: "*Prior Authorization* review will determine if the proposed *Service* is eligible as a *Covered Service*...." (SR 554).

II. Analysis

To be eligible for reimbursement, the BBBD treatment must be a covered benefit under the Policy. Lafferty has the burden of establishing that the BBBD treatment is a covered benefit under the Policy, and Providence bears the burden of establishing that an exclusion applies. Mario v. P&C Food Mkts, Inc., 313 F3d 758, 765 (2nd Cir 2002).

A. Covered Benefit

The parties dispute whether Lafferty's BBBD-enhanced high dose chemotherapy was a covered benefit under the Policy. The Policy defines "covered service" as a "*Service* that is: (1) listed as a benefit in the *Summary of Benefits* and in sections 5 and 6; (2) *Medically Necessary*; (3) Not listed as an exclusion in the *Summary of Plan Benefits* or in sections 5, 6, and 7; and Provided to *You* while *You* were a *Member* and eligible for the *Service* under this *Group Contract*." (SR 546). Lafferty argues that BBBD-enhanced chemotherapy is covered under the plan as it is made up of services which are listed as covered–such as chemotherapy, injectable medicines, and hospitalization.

(Plf.'s Opening Memo., pp. 24-25 (dkt. #27)). Providence counters that BBBD-enhanced treatment is not a covered service because Providence has deemed BBBD services experimental. (Defs.' Reply, p. 17-18 (dkt. #52)).

The record establishes that Lafferty received intra-arterial high dose methotrexate chemotherapy treatment for her tumor. (Supp. aff. of Edward A. Neuwelt, MD, ¶ 8 (dkt # 68)).[4] Chemotherapy is a covered benefit under the Policy. (SR 570). Hospital and skilled nursing services, including semi-private room accommodations, intensive care, medications, x-rays, and laboratory services are also covered under the Policy. (SR 569). Moreover, Providence recognizes high dose methotrexate is the "standard of care for treating primary central nervous system lymphoma" (SR 523). Lafferty's high dose methotrexate chemotherapy would have been performed in substantially the same manner even if the blood brain disruption drug Mannitol had not been used. (Supp. aff. of Edward A. Neuwelt, MD, ¶ 8 (dkt # 68)). She would have been admitted to the hospital the day prior to the procedure, the same evaluation and tests would have been performed, and the "following day, intra-arterial chemotherapy would have been given in the interventional radiology unit under anesthesia via an inter arterial catheter placed in a cranial artery." (Id.) Specifically, the evidence establishes that Lafferty's hospitalization was not required solely because of the BBBD treatment–which consisted of administering the drug Mannitol to disrupt the blood-brain barrier. Instead, hospitalization is required because of the potential toxicity of high dose methotrexate-based

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[4]The court has the discretion to allow additional evidence not before the Plan Administrator, but should exercise this discretion "only when circumstances clearly establish that additional evidence is necessary to conduct an adequate de novo review of the benefit decision." One such circumstance is where a claim "requires complex medical questions or issues regarding the credibility of medical experts." Opeta v. NW. Airlines Pension Plan, 484 F3d 1211, 1217 (9th Cir. 2007)(citation and internal quotation marks omitted).

chemotherapy. (Aff. Edward A. Neuwelt, MD, ¶ 30 (dkt. # 46). As previously noted, Providence recognizes high dose methotrexate-based chemotheraphy to be the "standard of care" for PCNSL. (SR 205, 424, 426, 523).

Based on the evidence in the record, I find that the Lafferty has met her burden of establishing that the following aspects of her treatment for PCNSL were covered under the policy: (1) her three day hospital stay; (2) any x-rays and/or MRI's; (3) her IV hydration; (4) her general anesthesia and intra-arterial cauterization to access an intra-cranial vessel; and (5) her intra-arterial Methotrexate and Carboplation. Providence's argument that its finding that the BBBD protocol was excluded from coverage as experimental/investigational excluded all of Lafferty's treatment for her PCNSL from coverage is not persuasive. It is obvious from the record that the Plan Administrator recognized that the standard of care for tumors such as Lafferty's was high dose methotrexate and that the BBBD was "a mechanism to permit the methotrexate to be effective." (Defs.' Surreply, p. 10 (dkt. # 101); SR 205, 424, 426, 523). Providence's refusal to pay for the aspects of Lafferty's treatment excepting the BBBD is especially troubling given Providence's reliance on the U.S. Centers for Medicare and Medicaid Services' National Coverage determination that

BBBD is not reasonably necessary when used as part of a treatment regimen for brain tumors when denying Lafferty's claim. (SR 491-508). Providence should have recognized that Medicaid's determination that BBBD is not necessary "does not alter in any manner the coverage of anticancer therapy." (SR 441). Indeed, the record establishes that Medicare covers its insured's cancer treatment charges, except for the charges for Mannitol. (Aff. Melissa Dhone, ¶ 6, Ex. A (dkt. # 69)).

In light of Medicare's ability to separate out billing for BBBD from billing for covered cancer treatment services, Providence's assertion that it "did as best it could to distinguish what was related

to the BBBD protocol from what was not, and pay for that which was not experimental" is not at all convincing. I find that Providence abused its discretion by denying Lafferty coverage for services which were obviously covered (and considered by Providence to the be the standard of care) under the Policy. (Defs.' Surreply, p. 10 (dkt. #101)).

Next, I consider whether Lafferty has established that the BBBD treatment, which consists of the drug Mannitol, is a covered benefit. As I previously noted, Lafferty bears the burden of establishing that Mannitol is a covered benefit and Providence bears the burden of establishing that it is experimental/investigational. Mario, 313 F3d at 765. I am mindful that the Policy definition of "covered service" means that "a service must not be listed as an exclusion in the *Summary of Benefits* or in sections 5, 6, and 7." (SR 546). Section 7 is a catch-all general exclusion provision which excludes, among other things, services which are "*Experimental/Investigational*." (SR 580). To reconcile the Policy language with the applicable case law–which places the burden of establising that a service is excluded as experimental or investigational on Providence, I will consider whether Lafferty has established that BBBD is a covered service without regard to the whether it is listed as an exclusion. Thus, to establish that BBBD is a covered service, Lafferty must establish that it is: "Listed as a benefit in the *Summary of Benefits* in sections 5 and 6; *Medically Necessary*; and (3) Provided to *You* while *You* are a *Member* and eligible for the *Service* under this *Group Contract.*" (SR 546).

It is undisputed that BBBD is not listed as a benefit in the Policy's *Summary of Benefits.* It is similarly undisputed that the BBBD services were provided to Lafferty while she was a member and eligible for service under the Policy. Accordingly, my inquiry in this de novo review will focus on whether Lafferty has established that the BBBD drug Mannitol was medically necessary and that

BBBD is thereby a covered service.

The Policy defines "medically necessary" as "[*s*]*ervices* that are in the reasonable opinion of *Providence Health Plan*, consistent with the written criteria regarding medically indicated *Services* that are maintained by *Us*. (SR 552). "The Criteria are based on the following principles:

1. The *Service* is medically indicated according to the following factors;
   - The *Service* is necessary to diagnose or to meet the reasonable health needs of the *Member;*
   - The expected health benefits from the *Service* are clinically significant and exceed the expected health risks by a significant margin;
   - The *Service* is of demonstrable value and that value is superior to other *Services* and to the provision of no *Services;* and
   - Expected heath benefits can include:
     a. Increased life expectancy;
     b. Improved functional capacity;
     c. Prevention of complications; or
     d. Relief of pain.
2. The treating physician recommends the *Service*.
3. The *Service* is rendered in the most cost-efficient manner and type of setting consistent with nationally recognized standards of care, and with consideration for potential benefits and harms to the patient.
4. The *Service* is consistent in type, frequency and duration with scientifically based guidelines of national medical, [sic] research or health care coverage organizations or governmental agencies that are accepted by *Us*.

(SR 552). The record is clear that Lafferty's treating physician recommended BBBD treatment to enhance her cancer treatment. (SR 84-85). I note the following facts about chemotherapy enhanced with BBBD therapy are particularly noteworthy. First, high dose chemotherapy combined with BBBD results in little to no cognitive loss; in contrast, high dose chemotherapy combined with radiation results in cognitive loss, especially to patients over 60 years of age. (Aff. Edward A. Neuwelt, ¶¶ 17-18, 36 and Ex. B (dkt. #46); SR 84-85, 438, 402-403, 235-237, 303-305). Next, when high dose chemotherapy is delivered without using the BBBD drug, it is given in higher doses, which creates a greater risk of systemic toxicity especially bone marrow suppression, renal failure and

leukoencephalopathy. (Aff. Edward A. Neuwelt, ¶ 33 and Ex B (dkt. #46)).

A through examination of the record establishes that the BBBD treatment meets the criteria for medically necessary services under the Policy as it has clearly significant health benefits, is of demonstrable value that exceeds other services, and expected health benefits include prevention of complications and improved functional capacity. (SR 552). Moreover, the service is consistent with scientifically based guidelines of national medical research and rendered in a cost efficient manner in a type of setting consistent with nationally recognized standards of care. (SR 522). I am mindful that Dr. Neuwelt is involved in the research and articles which form the basis for these conclusions; however, Dr. Neuwelt is one of the pioneers of research in this area so it is only natural that he would be involved in the majority of research and scholarship in this highly specialized area. I note that Dr. Neuwelt's conclusions and scholarship are reviewed and accepted by his peers. (Aff. Edward A. Neuwelt, MD, ¶¶10-11 (dkt # 46); SR 260-401). I cannot conclude that Dr. Neuwelt's research on this relatively rare type of brain tumor should be rejected simply because he is also Lafferty's treating physician. In short, I find that upon de novo review, Lafferty has established that BBBD treatment is medically necessary and thus covered under Providence's Policy. I next consider whether Providence has met its burden of establishing that BBBD is excluded from coverage as investigational/experimental.

B. Experimental/Investigational

As previously noted, the Policy defines "experimental/investigational" as follows:

Experimental/Investigational means those services that are determined by *Us* not to be *Medically Necessary* or accepted medical practice in the *Service Area*, including *Services* performed for research purposes. In determining whether *Services* are *Experimental/Investigational*, *We* will consider whether the *Services* are in general use in the medical community in the U.S.; whether the *Services* are under continued scientific testing and research; whether the *Services* show a demonstrable benefit

for a particular illness or disease; whether they are proven to be safe and efficacious; and whether they are approved for use by appropriate governmental agencies. We determine on a case-by-case basis whether the requested *Services* will result in greater benefits than other generally available *Services*, and will not approve such a request if the *Service* poses a significant risk to the health and safety of the *Member*. We will retain documentation of the criteria used to define a *Service* deemed to be *Experimental/Investigational* and will make this available for review upon request.

(SR 550)(italic in original).

Providence argues that BBBD treatment is experimental or investigational, as those terms are defined by the Policy, because it is not in general use in the medical community in the United States. In making this determination, Providence relied on expert opinions, the NCCN Guidelines, the National Cancer Institute PDQ, and the United States Centers of Medicare and Medicaid Services' National Coverage Determination for BBBD Chemotherapy. I note that the United States Centers of Medicare and Medicaid Service's determination was that BBBD was not reasonably necessary for treatment of cancer and did not opine on whether such treatment was in general use in the medical community in the United States. Next, I note that Providence's "expert opinions" were from physicians who are not experts in this highly specialized area.[5] Lafferty has presented evidence that BBBD-enhanced chemotherapy is performed at six specialized centers in the U.S. (Aff. Edward A. Neuwelt, MD, ¶ 11 (dkt. #46)). Second, Providence has conceded that BBBD-enhanced chemotherapy is used in the local medical community. (SR 525). Third, Lafferty has produced a raft of scientific articles to contradict the notion that BBBD is experimental or investigational. (SR 260-401). Based upon a through examination of this record, I find that the weight of the evidence demonstrates that BBBD therapy is firmly supported by decades of research and application and is

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[5]Moreover, with the exception of Dr. Flood, Providence's experts were employees of Providence. For example, Walter Urba, MD is the Director of Providence's Robert W. Franz Cancer Research Center, which is in direct competition with OHSU in cancer care. (SR 468, 478).

a well-established treatment for PCNSL. Moreover, because he is an expert in this highly-specialized field, Dr. Neuwelt's opinion is more persuasive than that of Providence's experts.

Second, Providence argues that BBBD-enhanced treatment is under continued scientific testing and research. The parties agree that this is the case. However, all treatments for PCNSL are under continued research and treatment because this disease is so rare that there have been no Phase III trials for its treatment. In short, there is no gold standard of treatment for PCNSL. (SR 84-85). Given that there are no Phase III trials for any treatment for this type of cancer, I cannot find that Providence has established that BBBD-enhanced chemotherapy is experimental simply because it is under continued testing and research.

Third, Providence argues that BBBD has not been shown to produce a demonstrably higher benefit in the treatment of PCNSL than a high dose chemotherapy alone or combined with radiation. In support of this assertion, Providence relied heavily on its expert Dr. Urba's opinion that the Phase II trials conducted to date on chemotherapy enhanced with BBBD are not convincing of the superiority or the equality of this treatment compared to high dose chemotherapy with or without radiation. This statement is contradicted by evidence in the record. Specifically, Dr. Neuwelt noted that the results from a series of patients treated over a 26-year period "demonstrates that BBBD/IA methotrexate-based chemotherapy results in successful and durable tumor control and outcomes that are comparable and superior to other PCNSL treatment regimes. (Aff. Edward A. Neuwelt, MD, ¶ 14 (dkt. #46)). I find that the opinion of Dr. Neuwelt, a recognized expert in this specialized field, is more convincing than that of Dr. Urba. Additionally, the record contains articles which demonstrate that the 5-year survival rates associated with BBBD-enhanced chemotherapy are higher than survival rates associated with high dose chemotherapy alone. (SR 26, 255, 261). Providence has failed to

show that BBBD-enhanced chemotherapy is not superior to high dose chemotherapy alone.

Fourth, Providence contends that BBBD-enhanced chemotherapy has not been proven to be safe and efficacious. Providence relied on its experts being unable to confirm that the disruption of the blood brain barrier for purposes of intra-arterial chemotherapy was safe. (Defs' Memorandum, p. 31 (dkt. # 33)). Providence also stated that its independent research failed to convince it that BBBD was safe. This too is contradicted by the record. BBBD-enhanced chemotherapy has an acceptable toxicity profile. (SR 258). OHSU's protocols were approved by the Oregon Cancer Center, which is an NCI approved center. (SR 85). Further, the Centers for Medicare and Medicaid Services, also referred to in the record as CMS, has stated that "BBBD used as part of a treatment regimen for brain tumors is acceptably safe when performed by experienced physicians in large, regional centers." (SR 495). Providence has not established that BBBD-enhanced chemotherapy is not safe and efficacious.

Finally, Providence argues that BBBD-enhanced chemotherapy is not approved by government agencies such as the U.S. Centers for Medicare and Medicaid Services. It is established in the record that the Centers for Medicare and Medicaid Services has concluded that BBBD-enhanced chemotherapy is not reasonable and necessary for the treatment of brain tumors. (SR 491-508). As such, reimbursement for the BBBD drug is not approved. As noted above, however, the Centers have concluded that BBBD is "acceptably safe when performed by experienced physicians in large, regional centers." (SR 495). Providence has established that BBBD drugs are not approved for coverage by governmental agencies.

Given the use of the word "and" in the Policy's definition of "experimental/investigational," I cannot conclude that Providence's establishment of only one of the criteria in the definition is

dispositive of a service being investigational/experimental. Thus, I find that Providence has not met its burden of establishing that BBBD drugs are an experimental treatment. Accordingly, Providence must cover the Mannitol used to enhance Lafferty's high dose chemotherapy.

Findings of Fact

1. Lafferty's high dose chemotherapy is a covered benefit under the Policy.

2. Providence has failed to establish that Mannitol, the Blood-Brain-Barrier Drug used to enhance Lafferty's high dose chemotherapy, is experimental.

Conclusions of Law

1. Lafferty's high dose BBBD-enhanced chemotherapy does not fall within any exclusions under the applicable Policy and is therefore a covered benefit.

2. Under the terms of the Policy, Lafferty is entitled to coverage for her high dose BBBD-enhanced chemotherapy.

Order

Lafferty's Motion for Summary Judgment (document #26) is GRANTED and Providence's and Eugene Freezing and Storage's Cross Motion for Summary Judgment (document #32) is DENIED.

In her complaint, Lafferty seeks benefits pursuant to her Policy plus her costs and attorneys fees. It is not clear from the filings what costs Lafferty has incurred to date for her BBBD-enhanced high dose chemotherapy. For example, Providence asserts that it has already processed payment for at least two of Lafferty's BBBD-enhanced chemotherapy sessions. Accordingly, within 21 days of the date this opinion and order is filed, the parties shall submit to the court a stipulated statement of the benefits payable pursuant to Lafferty's Policy.

IT IS SO ORDERED

DATED this 12th day of April 2010.

THOMAS M. COFFIN
United States Magistrate Judge